THERMO FISHER - SMART DON QUANTITATIVE TEST

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GENERAL INFORMATION

The Thermo Fisher Scientific SMART DON Test kit product number 600125-DON is a rapid enzyme immunoassay incorporating ready-to-use liquid reagents. Similar to a standard ELISA, the test is based on the competition of an enzyme bound DON conjugate and free DON from an extracted grain sample.

The instructions presented in this document cover only the procedure for performing the analytical test for official inspections. For questions regarding this procedure, contact Dr. Ajit Ghosh of the Technology and Science Division by phone at 816-891-0417 or email at Ajit.K.Ghosh@usda.gov.

Refer to the current policies and/or instructions issued by the Policies, Procedures, and Market Analysis Branch (PPMAB) of the Field Management Division for information on use of this test kit in official inspections including sampling, general sample preparation (e.g., grinding and dividing), reporting and certification of test results, laboratory safety, and hazardous waste management. For questions regarding these policies and/or instructions, contact Patrick McCluskey of PPMAB by phone at 816-659-8403 or email at Patrick.J.McCluskey@udsa.gov.

Approved Test Kit Information

Test Kit Vendor:	Thermal Fisher Scientific 1-800-282-4075
Test Kit Name:	SMART DON Test
Product Number:	600125-DON
Effective Date of Instructions:	03/30/2015
Instructions Revision Number	0
Conformance Range:	0.5 – 5.0 ppm
Number of Analyses to Cover Conformance Range:	1
Type of Service:	Quantitative
Supplemental Analysis:	No
Approved Commodities:	Wheat, corn, barley, and malted barley.
Extraction method:	Shake vigorously 50 grams ground sample with 250 milliliters (mL) of deionized or distilled water for 1 minute.
Test Format:	Rapid enzyme immunoassay.
Detection Method:	SMART DON Reader.

PREPARATION OF TESTING MATERIAL

1. Allow reagents to reach room temperature prior to running the test approximately 1 hour to bring to room temperature.

2. Plug in the SMART DON Analyzer. Wait for the SMART DON Analyzer to warm up approximately 15 minutes. To reactivate just re-touch the touch screen.

EXTRACTION PROCEDURES

1. **Extraction Procedure for wheat, corn, barley, and malted barley**

   a. Place 50 grams (+/- 0.2) of ground sample into a clean container.

   b. Add 250 mL of distilled or deionized water and close securely to prevent spillage.

   c. Shake vigorously over a mechanical shaker at 300 rpm for 3 minutes.

   d. Transfer 1 mL of the aliquot/mixture with a disposable transfer pipette to a micro centrifuge tube. Tube should be nearly full. Use a new pipette tip for each sample.

   e. Cap all tubes and place into the mini-centrifuge (all tubes must be suitably counter-balanced) and Spin the tubes for 1 minute.

   f. Collect sample aliquot and proceed to Test Procedures.

TEST PROCEDURES

Initiate the SMART DON Software and follow the step by step prompts as displayed on the computer screen.

1. Take Reagent A vial and place it into sample rack. Carefully remove the Reagent A lid (avoid spilling reagent).

   a. Using a single or multi –channel pipettor dispense 100 µL of Reagent A into vial.

   b. Using a single or multi – channel pipettor dispense 400 µL of distilled or deionized water into Reagent A into vial.

   c. Insert Reagent B cap into Reagent A vial cap and secure tightly. (**Do not shake or invert vial)**

2. Take the RFID card from the test package and insert it to the analyzer. (The analyzer reads the information from the card and shows the type of test, the number of remaining tests and the expiration date.) Touch  button. The door opens automatically. The entry menu appears on the screen. To navigate in the entry menu use up and down cursor.

3. Touch  button. The ABC menu displays on the screen. To navigate in the ABC menu touch Aa SYM button for upper, lower case, and special characters.

4. Enter name (ABC) and sample ID (numeric), confirm with  button. To delete letter(s) or number(s) use  button. To close a menu or to cancel an entry use  icon.

5. Insert the test cartridge. Touch ▶ button. The door closes and the analyzer processes the test for 5 minutes.

6. When the run is complete, the door opens. Remove the test cartridge and discard it.

7. Result menu displays on the screen.

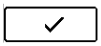
8. Choose one of the following options in Result menu:

   a. Touch  to print the result(s).

   b. Touch  to transmit the result(s) to a Personal Computer (PC).

   c. Touch  to view the chart.

   d. Touch  to delete the result(s).

   e. To close the menu touch  button.

9. Record results on the work record. Repeat steps for additional samples.

REPORTING AND CERTIFYING TEST RESULTS

Refer to the current instructions issued by the Policies, Procedures, and Market Analysis Branch of the Field Management Division for reporting and certification of test results. For questions regarding these instructions, contact Patrick McCluskey (816-659-8403 or Patrick.J.McCluskey@udsa.gov).

EQUIPMENT AND SUPPLIES

1. Materials Supplied in Test Kits: SMART DON test kit.

   a. Micro-plate, vials (part #600125-DON).

   b. Reagent A vials containing antibody/substrate reagent.

   c. Reagent B vials containing enzyme reagent.

2. Hardware Supplied for test kits: SMART DON test kit.

a. SMART DON Reader.

b. SMART DON Software program.

c. 100 µL multi-channel pipettor.

d. 385 µL single channel pipettor.

e. Mini-centrifuge.

f. Micro-centrifuge tube rack.

3. Consumables Supplied by Thermal Fisher.

a. Micro-centrifuge tubes.

b. Disposable transfer pipettes.

c. 100 µL pipette tips.

d. Test cups.

4. Materials Required but not supplied by Vendor.

a. Sealable containers for sample extraction and extract collection.

b. Distilled or deionized water.

STORAGE CONDITIONS AND PRECAUTIONS

1. Storage Conditions.

a. The reagents supplied with the test kit can be used until the expiration date on the kit label when refrigerated at temperatures between 36° F and 46° F.

b. Temperature range for optimal testing performance is ambient temperature (18 – 30 ° C (64 ° F to 86 ° F).

2. Precautions.

a. Perform the test with clean hands.

c. Always keep the box of reagents right-side up.

d. You may leave the reader plugged in at all times, it goes into a sleep mode after 10 minutes and can be awakened by swiping your finger across the screen.

e. When unscrewing the yellow cap from the Reagent A vial, be sure not to leave a smudge

on the bottom third of the vial. This is where the reading takes place. A Kim-wipe can be used to clean this section.

f. After unscrewing the cap from Reagent A vial, if there is a bubble covering the hole then use a pipette tip to burst the bubble. Then use a fresh tip to dispense either sample or water.

g. Pipette sample and water straight down into the Reagent A vial.

h. Once the Reagent B cap has been secured to the Reagent A vial, don't shake or invert the vial.

i. You may secure the Reagent B cap tightly while the sample is waiting to be analyzed.

j. Be sure the vial is properly positioned all the way into the slot on the reader.

REVISION HISTORY

Revision 0 (03/30/2015)